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EXAMINER	
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1657	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,321	REESLEV ET AL.	
	Examiner	Art Unit	
	PAUL C. MARTIN	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *46 and 47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/31/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-47 are pending in this application.

Election/Restrictions

Applicant's election with traverse of Group I (Claims 1-45) and of the Species (contaminants: bacteria), (liquid medium: environmental water), (enzyme: phosphatases) and (substrate: methylumbelliferyl derivative) in the reply filed on 08/14/08 is acknowledged. The traversal is on the ground(s) that the Examiner has not provided specifically where the Prior Art references teach or suggest the special technical feature. This is not found persuasive because Longoria (US 5,081,017) teaches the special technical feature of the claimed invention. That is a sterile filter **device** comprising a filter with a pore size sufficiently small to retain contaminants on the filter's influent side, means for passing a known volume of medium through the filter and at least one agent capable of releasing a detectable moiety. See the Abstract of Longoria wherein a **device** is taught comprising an inherently sterile filter which retains bacteria on its influent side and an agent which releases a detectable moiety (color) upon contact with the retained bacteria. As the invention makes no contribution over the Prior Art, wither the invention lacks unity of invention because the special technical feature is not found throughout all the groups (Groups I and III) or the special technical feature is not "special".

The Applicant suggests that Examiner has not provided specific reasons why the "subspecies" are patentably distinct and traverses the requirement for restriction between four separate Markush groups. This is not found to be persuasive because where a single claim defines alternatives of a Markush group, the requirement of a technical interrelationship and the same or corresponding technical features as defined by Rule 13.2, is considered met when the alternatives are of a similar nature. Alternatives are regarded as being of a similar nature where the following criteria are fulfilled:

a) all alternatives have a common property or activity; AND

b) a common structure is present, that is, a significant structural element is shared by the alternatives; OR

c) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class in the art to which the invention pertains. As discussed in the Prior Action the species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The contaminants are directed to different species of microorganisms sharing no common technical feature and having *different structures, habitats, activities and compositions*, the liquid mediums are unique from one another in terms of *composition and derivation*, the enzymes are *distinct in terms of structure, activity and preferred substrate*, and the substrates are *distinct in terms of structure and chemical composition*. That is, the alternatives lack a common property or activity and therefore restriction is proper.

Claims 46 and 47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 08/14/08.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-45 were examined on their merits.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

The use of the trademarks MILLI-Q™, MILLEX™ and NUCLEPORE™ has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claim 3 is objected to because of the following informalities: The word "Algae" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 contains the phrase, "…at least one substrate that through interaction with the contaminants each produces a detectable moiety…" It is unclear whether the interaction between the substrate and the contaminants produces one detectable moiety in each instance of interaction or whether the interaction produces multiple detectable moieties derived from both the substrate and the contaminants. Claims 2-45 are rejected as being dependent upon rejected Claim 1.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 17 refers to at least one substrate is a fluorogenic or chromogenic substrate producing blue, green and red fluorescent products as the detectable moiety. It is unclear how a chromogenic (color producing) substrate will produce a fluorescent product since not all chromogens produce substrates which are both colored in visible light as well as fluorescent light.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 19 recites the broad recitation, “wherein the detectable moiety is detectable in an amount of at the most 100 picomoles", and the claim also recites preferably at the most 50, 20, 10 and 1 picomoles” which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 7, 10-13, 16, 17, 20, 22-28, 35, 36 and 40-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Tuompo *et al.* (US 5,714,343).

Tuompo *et al.* teaches a method for the detection of viable microorganisms (bacteria), the method comprising a) passing a known volume of liquid medium through a filter from influent side to effluent side in a closed, sterile filter device (Fig. 1) thereby concentrating and retaining microorganisms (bacteria) present on the filter device influent side, b) contacting the influent side of the filter with a liquid vehicle (test solution) containing an enzyme substrate that through contact with constitutively expressed microbial dehydrogenase will produce a detectable moiety, and c) allowing the chromogenic substrate to interact with the microorganisms (bacteria) for a period of time wherein the interaction is not terminated and detecting the colored product retained on the filter and correlating the detection of the colored product to the presence of bacteria in the sample (Column 8, Claim 1 and Column 9, Claims 1, 2, 4, 5 and 7 and Column 4, Lines 66-67 and Column 5, Lines 1-25).

Tuompo *et al.* teaches wherein prior to step a) the medium is pre-filtered (Column 3, Lines 35-52), wherein the viscosity is reduced by means of dilution prior to step a) (Column 4, Lines 66-67), wherein the filter has a pore size from 0.75 to about 1.2 μm (Column 2, Lines 45-47), wherein several different known volumes of medium containing different amounts of bacteria were passed through a filter in step a) (Column 5, Table 1), wherein detection is performed in a microtiter plate (Column 5, Lines 5-7), wherein the bacteria are subjected to a selective pH incubation prior to step a) (Column 5, Table 1) and wherein the water soluble substrate MTT which is not retained on the fiber can be used for spectrophotometric methods of detection (Column 3, Lines 22-23).

Tuompo *et al.* teaches that the method can be used on liquid samples from the wood and pulp industry, the sugar industry or urban waste water (Column 2, Lines 30-33).

It is inherent in the method of Tuompo *et al.* that the liquid vehicle containing the chromogenic substrates comprises multiple substrates providing signals that are combined into one measured signal value, and that the amount of substrate does not limit the rate of production of the detectable moiety. It is inherent that the detectable moiety would be detected in the liquid vehicle as some liquid vehicle would inevitably be retained in the filter along with the substrate and colored product. It is further inherent that the rate of production of the detectable moiety would be a function of the quantity of bacteria in the medium as it logically follows that more bacteria would equal more available enzyme for reaction with the substrate and result in a greater rate of production over a sample containing less bacteria (the velocity of an enzyme catalyzed reaction is first order in enzyme concentration). It is an inherent property of the filter device of Tuompo *et al.* would be disposable as nearly everything can be considered "disposable", giving the term its broadest, reasonable interpretation and only depends on the materials used. It is inherent in the method of Tuompo *et al.* that the incubation would entail treatment with an enzyme inducing substance which would enhance the detection of the detectable moiety because enzymes operate most efficiently at specific pHs and the treatment with multiple ranges of pH would determine the optimal pH and enhance the detection of the detectable moiety.

Claims 1, 3, 4, 6, 7, 10, 11, 14-17, 20, 22-25, 27, 28, 35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Ralls *et al.* (US 5,741,659).

Ralls *et al.* teach a method for detecting viable bacteria in liquid samples, comprising: a) passing a known volume of liquid medium through a closed, sterile filter from influent to effluent side in a filter device thereby concentrating (retaining) the bacteria on the influent side of the filter device, b) contacting the influent side of the filter device with a liquid medium containing a chromogenic substrate that though cleavage by constitutively expressed protease enzymes produces a detectable moiety (color), and c) allowing the substrate to interact with the bacteria on the influent side of the filter for a period of time, detecting the detectable moiety and correlating the detection of the moiety to the presence of bacteria in the sample (Column 6, Lines 65-67 and Column 6, Lines 1-48 and Column 8, Claim 1).

Ralls *et al.* teaches a method wherein the viscosity of the liquid medium is reduced by dilution prior to step a) (Column 6, Lines 4-6).

It is inherent in the method of Ralls *et al.* that the liquid vehicle containing the chromogenic substrates comprises multiple substrates providing multiple signals that are combined into one measured signal value, and that the amount of substrate does not limit the rate of production of the detectable moiety. It is inherent in the method of Ralls *et al.* that the pore size of the filter, if sufficient to retain bacteria, would also therefore be large enough to let the detectable colored chromogenic product pass through as chemical molecules are orders of magnitude smaller than cells. It is inherent that the detectable moiety would be detected in the liquid vehicle as some liquid vehicle would inevitable be retained in the filter along with the substrate and colored product. It is further inherent that the rate of production of the detectable moiety would be a function of the quantity of bacteria in the medium as it logically follows that more bacteria would equal more available enzyme for reaction with the substrate and result in a greater rate of production over a sample containing less bacteria. It is an inherent property of the closed, sterile filter device of Ralls *et al.* would be disposable as nearly everything can be considered “disposable”, giving the term its broadest, reasonable interpretation.

Claims 1, 3, 4, 6, 7, 10, 11, 14, 15, 17, 20, 22-25, 27, 28, 31, 32, 33, 35 and 36 are rejected under 35 U.S.C. § 102(b) as being anticipated by Laine *et al.* (US 6,090,573).

Laine *et al.* teaches a method for detecting viable bacteria or fungi in liquid CSF samples, comprising: a) passing a known volume of diluted liquid medium through a closed, sterile filter from influent to effluent side in a filter device by positive pressure filtration thereby concentrating (retaining) the bacteria on the influent side of the filter device, b) contacting the influent side of the filter device with a liquid medium containing a chromogenic lysozyme-alkaline phosphatase or horseradish peroxidase conjugate detect reagent and an alkaline phosphatase or horseradish peroxidase substrate that though cleavage by bound enzymes produces a detectable moiety (color), and c) allowing the substrate to interact with the bacteria on the influent side of the filter for a period of time, detecting the detectable moiety by interrupting (eluting) contact between the substrate and detect reagent bound bacteria by evacuating the product from influent to effluent side of the filter and correlating the detection of the moiety to the presence of bacteria in the sample and comparing the data to standards (Column 45, Lines 58-67 and Column 46, Lines 1-30).

Laine *et al.* teaches that the method is applicable to biological samples including biological materials carried in the air or water (e.g. bacteria, fungi spores and the like) and collectable therefrom (Column 23, Lines 36-41).

It is inherent in the method of Laine *et al.* that the liquid vehicle containing the chromogenic substrates comprises multiple substrates providing multiple signals that are combined into one measured signal value, and that the amount of substrate does not limit the rate of production of the detectable moiety. It is inherent in the method of Laine *et al.* that the pore size of the filter, if sufficient to retain bacteria, would also therefore be large enough to let the detectable colored chromogenic product pass through as chemical molecules are orders of magnitude smaller than cells. It is inherent that the detectable moiety would be detected in the liquid vehicle as some liquid vehicle would inevitable be retained in the filter along with the substrate and colored product. It is further inherent that the rate of production of the detectable moiety would be a function of the quantity of bacteria in the medium as it logically follows that more bacteria would equal more available enzyme for reaction with the substrate and result in a greater rate of production over a sample containing less bacteria. It is an inherent property of the closed, sterile filter device of Laine *et al.* would be disposable as nearly everything can be considered “disposable”, giving the term its broadest, reasonable interpretation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 10-13, 16, 17, 20, 22-30, 35, 36 and 40-45 rejected under 35 U.S.C. 103(a) as being unpatentable over Tuompo *et al.* (US 5,714,343).

The teachings of Tuompo *et al.* were discussed above.

Tuompo *et al.* did not teach a method wherein the liquid sample was environmental water, wherein the closed, sterile filter device integrates the filter and filter housing into one irreversibly closed structural unit, wherein longest cross-sectional axis of the closed, sterile filter device does not exceed a length of 10cm.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Tuompo *et al.* for the detection of viable microorganisms (bacteria) in liquid samples to detect microorganisms in environmental water samples because Tuompo *et al.* teaches that the method is applicable to many varied liquid samples from biological fluids to industrial or waste water liquids as well as other liquid samples in which the presence of microorganisms is of interest. One of ordinary skill in the art would have been motivated to make this modification because the reference clearly teaches its suitability in assaying a wide range of liquid samples. While the reference does not teach the integration of the filter and filter housing into one irreversibly closed structural unit, wherein longest cross-sectional axis of the closed, sterile filter device does not exceed a length of 10cm, those of ordinary skill in the art would have recognized that making the structure irreversibly closed and of a certain cross-sectional length are merely artisinal design modifications dependent upon personal preference and do not materially change the way the device functions. There would have been a reasonable expectation in making these modifications because the reference clearly teaches the applicability of the method to assaying any liquid water samples suspected of containing microorganisms and because personal design choices of the devices used in biological methods are well known to those of ordinary skill in the art.

Claims 1-7, 10-13, 16, 17, 18, 20, 22-30, 35, 36, 37, 38 and 40-45 rejected under 35 U.S.C. 103(a) as being unpatentable over Tuompo *et al.* (US 5,714,343) in view of Koumura *et al.* (US 4,591,554).

The teachings of Tuompo *et al.* were discussed above.

Tuompo *et al.* does not teach a method wherein the substrate that produces a detectable moiety by being cleaved by an enzyme characteristic for the contaminants is a methylumbelliferyl derivative, wherein the detection step is performed by measuring fluorescence of the detectable moiety and wherein fluorescence is measured directly on the liquid vehicle without interruption.

Koumura *et al.* teaches a method wherein a liquid sample of viable microorganisms (bacteria, fungi, etc.) are contacted with methylumbelliferyl derivatives in a liquid vehicle that upon hydrolysis by enzymes characteristic to the microorganisms form fluorescent products which are measured directly in the liquid vehicle (Column 11, Claim 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the chromogenic filtration method for the detection of viable microorganisms (bacteria) as taught by Tuompo *et al.* with the use of methylumbelliferyl derivative substrates and direct measurement method of Koumura *et al.* because the use of fluorescent vs. chromogenic substrates in the detection of microorganisms is well known in the art. Both references teach the detection of bacteria with substrates which are either chromogenic or fluorogenic and which upon interaction with characteristic enzymes form either a colored or fluorescent product. Therefore, one of ordinary skill in the art would conclude that either substrate would be suitable for detection of microorganisms. The MPEP states:

> The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945)

Claims 1, 3, 4, 6, 7-11, 14, 15, 17, 20-25, 27, 28, 31-36 and 39 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Laine *et al.* (US 6,090,573).

The teachings of Laine *et al.* were discussed above.

Laine *et al.* does not teach a method wherein the gaseous medium is air, wherein at least one substrate includes at least two substrates that produce detectable moieties providing distinguishable signals, wherein evacuation is obtained by applying elevated pressure on the influent side of the filter or applying a lowered pressure on the effluent side of the filter or wherein the correlation comprises the use of a pre-determined standard curve that expresses the relationship between the amount of microorganisms and the amount of the detectable moiety under standard conditions.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Laine *et al.* to detecting microorganisms in air because the reference teaches that the method is suitable for the detection of airborne microorganisms collected from the air. Motivation to make this change would come from the teachings of the reference which teach the applicability of the method to detection of microorganisms from either air or liquid samples.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Laine *et al.* to utilize two substrates providing distinguishable signals because the reference teaches the detection method using two separate distinguishable signaling moieties and combination of the two substrates for the same purpose would flow naturally from the teachings.

The MPEP states:

> "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)

It would have been obvious to one of ordinary skill in the art at the time of the invention to evacuate (elute) the colored enzymatic reaction product by applying either an elevated pressure on the influent side of the filter or applying a lowered pressure on the effluent side of the filter because one of ordinary skill in the art would have recognized this as an automation of the gravity filtration process and the automation of a previously manual activity is *prima facie* obvious (See MPEP, *In re Venner*). Further, the reference teaches the use of positive pressure as a means of filtration of the samples and thus the use of positive or negative pressure to facilitate the movement of materials would have been obvious to those of ordinary skill in the art at the time of the invention.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a pre-determined standard curve in order to correlate the resultant data from the method of Laine *et al.* by comparison of the two because the use of standards and standard curves would have been well known to and within the purviuew of, those of ordinary skill in the art at the time of the invention.

The reference already teaches the comparison of data to standards and the further generation of a standard curves is routine in the art. One of ordinary skill in the art would have been motivated to make this modification because the use of standards and standard curves as a means of removing background or interfering data would improve the accuracy of the experimental data.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL C. MARTIN whose telephone number is (571)272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1657

10/07/08

/JON P WEBER/

Supervisory Patent Examiner, Art Unit 1657